JUN 24 2003

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510(k) SUMMARY

The following 510(k) summary is being submitted as required by 21 CFR 807.92(a):

Submission Information:

Contact: Patrick Moore
Manager, Quality Assurance

Sponsor: U&I America
6132 South 380 West
Murray, UT 84107
Phone: 801.262.3100
Fax: 801.262.3151

Date Prepared: June 11, 2003

Device Identification:

Trade Name: U&I America, Spinal Hook System™
Common Name: Spinal Hook System

Classification Name: Spinal Hook System

Appiliance, Fixation, Spinal Interlaminal (KWP) per 21 CFR § 888.3050

Substantially Equivalent Predicate Legally Marketed Devices:

United States Surgical Corporation, Rogozinski Spinal System – KWP, MNH, MNI, KWQ -- (K983804)
Cotrel-Dubousset (CD™) Spinal system -- MNH, MNI, KWQ, KWP -- (K001319, K955807)

The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the above listed predicate devices.

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Device Description:

The U&I America, Spinal Hook System ™ is a top-loading posterior spinal fixation system which consists of hooks, rods, set screws, connectors, and a transverse (cross) linking mechanism. The Spinal Hook System ™ implant components are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

The U&I America, Spinal Hook System ™ can be used in the posterior plane providing unilateral and bilateral modes of fixation.

The U&I America, Spinal Hook System ™ design allows adjustment in both the sagittal and coronal planes permitting hook placement according to the best possible anatomic (spinal) location and orientation.

Specialized instruments made from surgical instrument grade stainless steel are available for the application and removal of the Spinal Hook System ™ implants.

From the foregoing, we conclude that the subject U&I America, Spinal Hook System ™ device is as safe and effective as named predicates and currently marketed competitive devices for the stated indications.

Indications for Use:

The U & I Spinal Hook and Rod System intended for use as a posterior, noncervical, nonpedicle system indicated for degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudoarthrosis; and failed previous fusion.

The U & I Spinal Hook and Rod System can be used in conjunction with the OPTIMA Spinal System or the GLOBAL Spinal Fixation System.

Statement of Technological Comparison:

The subject spinal implant system is substantially equivalent to the above listed predicate devices in terms of materials, design, indications for use and operational principles.

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Performance Data:

Bench testing as listed in Section XII which was conducted in accordance with ASTM F1717 demonstrates equivalence to the above listed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2003

Mr. Patrick Moore
Manager, Quality Assurance
U&I America
6132 South 380 West, Suite 200
Murray, Utah 84107

Re: K031595
Trade Name: U&I America, Spinal Hook System™
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: II
Product Code: KWP
Dated: May 16 and June 10, 2003
Received: May 21 and June 12, 2003

Dear Mr. Moore:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031595

Device Name: U&I America, Spinal Hook System ™

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_____ **OR Over-the-Counter Use**_____**(Per 21 CFR 801.109)**
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031595